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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/892,403	07/15/97	MURPHY	B 17634-000510

HM22/0201  
TOWNSEND AND TOWNSEND AND CREW  
TWO EMBARCADERO CENTER  
8TH FLOOR  
SAN FRANCISCO CA 94111

16.  
EXAMINER

BRUMBACK, B

ART UNIT	PAPER NUMBER
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1643 /3

DATE MAILED: 02/01/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**08/892,403**

Applicant(s)  
**Murphy et al.**

Examiner  
**Brenda Brumback**

Group Art Unit  
**1643**



☒ Responsive to communication(s) filed on Nov 13, 1998

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-64 is/are pending in the application.

Of the above, claim(s) 11-46, 51-60, and 62-64 is/are withdrawn from consideration.

☒ Claim(s) 47-50 is/are allowed.

☒ Claim(s) 1-10 and 61 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-64 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 12

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### **DETAILED ACTION**

1. The examiner acknowledges the information disclosure statement (IDS) and the amendment filed 11/13/98 amending claims 1, 47, and 61 and adding new claims 63 and 64. A signed copy of the IDS is attached hereto. The examiner notes applicant's statement that claims 1-10, 47-50, 61, 63, and 64 are pending; however, pending claims are 1-64. Claims 11-46, 51-60, and 62 were withdrawn from consideration as drawn to a non-elected invention. Claims presently under consideration are 1-10, 47-50, 61, 63, and 64.

This application contains claims drawn to a nonelected invention. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Election/Restriction***

2. Amended claim 1 and newly added claims 63 and 64 are directed to inventions that are independent or distinct from the originally elected invention of Group I. The amendment filed 11/13/98 incorporates additional inventions as follows:

- I. Claims 2-10, drawn to recombinant respiratory syncytial viruses (RSV) with temperature sensitive amino acid substitutions and methods of making recombinant RSV, classified in class 424, subclass 199.1 and to claims 1, 47-50, and 61 to the extent that they read on claims 2-10.

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- II. Claims 13, 14, 27, 28, 52, and 53 drawn to recombinant RSV with a modified SH gene, classified in class 424, subclass 199.1 and to claims 1, 11, 12, 26, and 47-51 to the extent that they read on claims 13, 14, 27, 28, 52, and 53.
- III. Claims 20, 31-34, 54, 56-58, and 62 drawn to recombinant RSV with heterologous RSV genes, classified in class 424, subclass 199.1 and to claims 1, 11, 47-51, and 61 to the extent that they read on claims 20, 31-34, 54, 56-58, and 62.
- IV. Claims 21, 35, and 59 drawn to recombinant RSV with genome modifications to encode non-RSV proteins, classified in class 424, subclass 199.1 and to claims 1, 26, and 47-51 to the extent that they read on claims 21, 35, and 59.
- V. Claim 19, drawn to recombinant RSV with a nucleotide modification in a translational start codon, classified in class 424, subclass 199.1 and to claims 1 and 11 to the extent that they read on claim 19.
- VI. Claims 18 and 38, drawn to recombinant RSV with a nucleotide modification in a termination codon or a GS or GE transcription signal, classified in class 424, subclass 199.1 and to claims 1 and 11 to the extent that they read on claims 18 and 38.
- VII. Claims 22-25, 36, 37, and 60, drawn to recombinant RSV with a parainfluenza (PIV) gene classified in class 424, subclass 199.1 and to claims 1, 11, 30, 47-51, 54, and 55 to the extent that they read on claims 22-25, 30, 36, 37, and 60.

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- VIII. Claims 15-17, 29, 30, and 54 drawn to recombinant RSV with a nucleotide modification to a cis-acting regulatory sequence classified in class 424, subclass 199.1 and to claims 1, 11, 30, 47-51, and 55 to the extent that they read on claims 15-17, 29, 30, and 54.
- IX. Claims 39-46, drawn to a vaccine and methods of stimulating the immune system, classified in class 199.1, subclass 199.1 and to claims 26 and 38 to the extent that they read on claims 39-46.
- X. Claims 1, 63, and 64, drawn to recombinant RSV with mutations adopted from different biologically-derived RSV strains, classified in class 424, subclass 199.1,
- XI. Claims 1, 63, and 64, drawn to recombinant RSV with a restriction marker, classified in class 424, subclass 199.1;
- XII. Claims 1, 63, and 64, drawn to recombinant RSV with a mutation in a 3' promoter element that enhances RSV replication, classified in class 424, subclass 199.1.

The inventions of Groups I-IX are distinct for the reasons of record in Paper # 6. The products of X, XI, and XII are different products, having different structures. Because these inventions are distinct for the reason given and the search required for Groups X, XI, and XII is not required for Groups I-IX, restriction for examination purposes as indicated is proper.

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Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. See 37 CFR 1.142(b) and MPEP § 821.03.

***Claim Rejections - 35 USC § 102/103***

3. The rejection of claims 1-7, 9, 10, and 61 under 35 U.S.C. 102(b) as being anticipated by or in the alternative under 35 U.S.C. 103(a) as unpatentable over Murphy et al.; the rejection of claims 1-3, 10 and 61 under 35 U.S.C. 102(b) as being anticipated by or in the alternative under 35 U.S.C. 103 (a) as unpatentable over Crowe et al.; and the rejection of claim 8 under 35 U.S.C. 103(a) as being unpatentable over Murphy et al. in view of Wathen et al are all withdrawn due to applicant's amendment of the additional limitation of "...multiple nucleotide changes in a codon specifying the temperature sensitive substitution" and the arguments pertaining to this limitation, which were persuasive.

***Allowable Subject Matter***

4. Claims 47-50 are allowed. Applicant's arguments were persuasive.

***NEW GROUNDS OF REJECTION***

***Claim Objections***

5. Claims 1-10 and 61 are objected to as reciting non-elected inventions. Amendment of

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claim 1 to include only the additional limitation of "...multiple nucleotide changes in a codon specifying the temperature sensitive substitution" and to delete the remainder of the claim amendments drawn to inventions X, XI, and XII would make claims 1-10 and 61 also allowable.

*Conclusion*

6. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Brumback whose telephone number is (703) 306-3220. If the examiner can not be reached, inquiries can be directed to Supervisory Patent Examiner Chris Eisenschenk whose telephone number is (703) 308-0452. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose

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telephone number is (703) 308-0196. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Brenda Brumback, Art Unit 1643 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1643 FAX telephone number is (703)-305-3014. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

Brenda Brumback  
January 27, 1999



DONNA WORTMAN  
PRIMARY EXAMINER